

**Summary Minutes of the
Tobacco Products Scientific Advisory Committee
March 30-31, 2010**

Location: Holiday NTSB Conference Center, 429 L'Enfant Plaza, S.W. Washington, D.C.

All external requests for the meeting transcripts should be submitted to the CTP, Freedom of Information office.

These summary minutes for March 30-31, 2010 Meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration were approved on June 8, 2010.

I certify that I attended the March 30-31, 2010 meeting of the Tobacco Products Scientific Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

**_____/s/_____
Cristi Stark, M.S.
Acting, Designated Federal Official, TPSAC**

**_____/s/_____
Jonathan Samet, M.D., M.S.
Committee Chair, TPSAC**

Meeting of the Tobacco Products Scientific Advisory Committee March 30-31, 2010

The Tobacco Products Scientific Advisory Committee of the Food and Drug Administration, Center for Tobacco Products met on March 30-31, 2010 at the NTSB Conference Center, 429 L'Enfant Plaza, S.W. Washington, D.C. Prior to the meeting, members and invited consultants were provided copies of the background material from the FDA and the submissions from the public. The meeting was called to order by Jonathan Samet, M.D., M.S. (Committee Chair); the conflict of interest statement was read into the record by Cristi Stark, M.S. (Acting, Designated Federal Official). There were approximately 250 persons in attendance. There were 11 speakers for the Open Public Hearing session.

Issue: On March 30, 2010, the committee received presentations on the background and overview of the FDA Center for Tobacco Products, the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act), and the Tobacco Products Scientific Advisory Committee; and 2) received presentations on and discussed the published literature on menthol as it relates to the demographics of users, preferential use by persons initiating tobacco use, the health effects of menthol in cigarettes, the effects of menthol on addiction and cessation, marketing and consumer perceptions about menthol cigarettes, the sensory qualities of menthol cigarettes, and the effects of menthol on how cigarettes are smoked. On March 31, 2010, the Committee continued the presentations and discussions of topic 2; and also received preliminary information about topics planned for discussion at future meetings, including the establishment of a list of harmful and potentially harmful tobacco product constituents, including smoke constituents.

Attendance:

March 30, 2010:

Tobacco Products Scientific Advisory Committee Members Present (Voting):

Jonathan Samet, M.D., M.S. (Committee Chair)
Neal Benowitz, M.D.
Mark Clanton, M.D., M.P.H.
Gregory Connolly, D.M.D., M.P.H.
Karen DeLeeuw, M.S.W. (State/Local Government)
Dorothy Hatsukami, Ph.D.
Patricia Nez-Henderson, M.P.H., M.D. (Public Representative)
Jack Henningfield, Ph.D.
Melanie Wakefield, Ph.D.

Industry Representative Members Present (Non-voting):

Luby Arnold Hamm (Tobacco Growers Representative)
Daniel Heck, Ph.D, D.A.B.T. (Tobacco Manufacturing Industry Representative)
John Lauterbach, Ph.D., D.A.B.T. (Small Business Tobacco Manufacturing Industry Representative)

Ex Officio Members Present (Non-Voting):

Ursula Bauer, Ph.D., M.P.H. (CDC)
H. Westley Clark, M.D., J.D., M.P.H. (SAMHSA)
Robert Croyle, Ph.D. (NIH)

FDA Participants (Non-Voting):

Lawrence Deyton, M.S.P.H., M.D.
Corinne Husten, M.D., M.P.H.

Acting, Designated Federal Official:

Cristi Stark, M.S.

March 31, 2010:

Tobacco Products Scientific Advisory Committee Members Present (Voting):

Jonathan Samet, M.D., M.S. (Committee Chair)
Neal Benowitz, M.D.
Mark Clanton, M.D., M.P.H.
Gregory Connolly, D.M.D., M.P.H.
Karen DeLeeuw, M.S.W. (State/Local Government)
Dorothy Hatsukami, Ph.D.
Patricia Nez-Henderson, M.P.H., M.D. (Public Representative)
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Ex Officio Members Present (Non-Voting):

Ursula Bauer, Ph.D., M.P.H. (CDC)
H. Westley Clark, M.D., J.D., M.P.H. (SAMHSA)
Susan Karol, M.D. (IHS)

FDA Participants (Non-Voting):

Lawrence Deyton, M.S.P.H., M.D.
Corinne Husten, M.D., M.P.H.

Acting, Designated Federal Official:

Cristi Stark, M.S.

Open Public Hearing Speakers:

Katherine Swartz
William R. True, Lorillard Tobacco Company
Brandel France de Bravo, National Research Center for Women and Families
Cheryl Heaton, Legacy
Pamela Clark, School of Public Health at University of Maryland & Phillip Gardiner, University of California
Michael W. Ogden, R.J. Reynolds Tobacco Co.
Susanne E. Tanski, American Academy of Pediatrics
James E. Dillard III, Altria Group
Jim Tozzi, Center for Regulatory Effectiveness
Jeannette Noltenius, National Latino Tobacco Control Network
Marcia DeFalco, General Dynamics IT

The agenda was as follows:

March 30, 2010

Call to Order and Introductions

Jonathan Samet, M.D., M.S.

Committee Chair

Tobacco Products Scientific Advisory Committee

Conflict of Interest Statement

Cristi Stark, M.S.

Acting, Designated Federal Official

Tobacco Products Scientific Advisory Committee

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HHS/FDA Speeches

Howard Koh, M.D., M.P.H.

Assistant Secretary for Health, HHS

Margaret Hamburg, M.D.

Commissioner, FDA

Lawrence Deyton, M.S.P.H., M.D.

Director, CTP, FDA

FDA Presentation

Introduction to Family Smoking
Prevention and Tobacco Control
Act (the Tobacco Control Act),

Catherine Lorraine, J.D.

Lead Counselor, CTP, FDA

Introduction to Tobacco Products
Scientific Advisory Committee
(TPSAC),

Corinne Husten, M.D., M.P.H.

Senior Medical Advisor, CTP, FDA

Secretary of HHS Required Report
“The Impact of the Use of Menthol
In Cigarettes on the Public’s Health”

Corinne Husten, M.D., M.P.H.

Questions to the Presenters

Guest Speaker

Use of Menthol Cigarettes by
Demographic Groups

Ralph Caraballo, Ph.D, M.P.H.

Epidemiology Branch Chief, OSH, CDC

FDA Presentation

Menthol Sensory Qualities,
Topography

Deirdre Lawrence, Ph.D., M.P.H.

CTP (on detail from National Cancer Institute (NCI)/NIH)

Questions to Presenters

Consumer Perceptions of
Menthol Cigarettes

Joshua Rising, M.D., M.P.H.

CTP

Menthol Cigarettes and Smoking

Joshua Rising, M.D., M.P.H.

Initiation

Menthol Cigarettes and Nicotine
Dependence

Allison Hoffman, Ph.D.
CTP (on detail from National Institute on Drug Abuse
(NIDA)/NIH)

Menthol Cigarettes and Smoking
Cessation

Allison Hoffman, Ph.D.

Potential Health Effects of
Menthol

Allison Hoffman, Ph.D.

Questions to Presenters

Adjourn

The session adjourned @ approximately 3:49 p.m.

March 31, 2010

Call to Order and Introductions

Jonathan Samet, M.D., M.S.
Committee Chair
Tobacco Products Scientific Advisory Committee

Conflict of Interest Statement

Cristi Stark, M.S.
Acting, Designated Federal Official
Tobacco Products Scientific Advisory Committee

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Recap of March 30, 2010

Additional Questions to Presenters

Open Public Hearing

Questions to the TPSAC Committee
and TPSAC Discussion

FDA Presentation

Topics Planned for Future
Meetings

Corinne Husten, M.D., M.P.H.

Question to the Presenters

Closing Remarks

Adjourn

The session adjourned @ approximately 2:58 p.m.

Questions to the committee:

1. (Discussion) Are there any specific questions around menthol that industry should address at the next meeting?

- *The committee compiled a list of items for industry to present at the next meeting by five general topic areas:*

Characterization of menthol – recommended as a topic for the next TPSAC meeting

- 1) *Menthol content by brand (mentholated and non-mentholated), including changes over time
 - a. If available, including menthol and nicotine content in the cigarette rod and cigarette smoke as measured by FTC/ISO standards
- 2) *Qualitative description and industry understanding of menthol, including a description of the manufacturing mechanism for introducing menthol to the tobacco product
 - a. Sources of menthol
 - b. Potential analogs of menthol
- 3) *Industry threshold for defining a characterizing effect of menthol
- 4) Industry motivation and justification for the addition of menthol to cigarettes
- 5) *American Indian industry manufacturers of mentholated cigarettes
- 6) *International experience around use and marketing of mentholated products

Clinical effects of menthol – recommended as a topic for the next TPSAC meeting

- 7) *Dose-response curves on physiologic responses to varying levels of menthol concentration, by gender, ethnicity and age
- 8) *Mechanistic studies of menthol effects
 - a. Chemosensory effects of natural and synthetic menthol compounds, including thermal and trigeminal receptor interactions
 - b. Neurobiology
 - c. Clinical and behavioral
- 9) *Studies directed at dosing and metabolic interactions between nicotine and menthol, including resulting perceptions of nicotine strength
 - a. Analysis of interaction between menthol delivery and nicotine/tar levels, for both low-menthol and high-menthol products
- 10) *Consumer perception data around menthol product and smoke taste (e.g., smoothness and harshness) by menthol level, including relationship to consumer perceptions of product harm (e.g., focus group, qualitative panel research)

Biomarkers – recommended as a topic for the next TPSAC meeting

- 11) *Laboratory and population analysis of biomarkers related to menthol content and daily cigarette consumption
 - a. Unpublished biomarker studies related to menthol by subgroup (Altria study)

Marketing data – recommended as a topic for a later TPSAC meeting

- 12) *Consumer preference data
- 13) *Consumer perception studies around advertising and packaging claims

- a. Qualitative research around marketing terms for menthol products (e.g., fresh, mint)
- 14) Marketing of new products (e.g., Crush)
- 15) *Marketing of products by brand and subbrand, according to gender, race and age
 - a. Existence and nature of targeted marketing strategies
 - b. Marketing expenditures and unit sales over time (e.g., commercial sources of retail data)
- 16) *Marketing strategies aimed at expanding market share, including promotion of initiation and recruitment of former smokers

Population effects – recommended as a topic for a later TPSAC meeting

- 17) *Quantitative data around use
 - a. Rates of switching menthol to nonmenthol cigarettes by brand/subbrand and population group, as available
 - b. Comparative rates of initiation for menthol cigarettes vs nonmenthol cigarettes by brand/subbrand and population group, as available
 - c. Comparative rates of cessation among menthol smokers as compared to nonmenthol smokers, by brand/subbrand and population group as available

* - considered by the TPSAC to be a high priority topic

Please see the transcript for detailed discussion.

- 2. (Discussion) What other information does the Committee need in order to meet its statutory requirement?

- *The committee compiled a list of items to aid in their efforts for the required report of menthol in cigarettes on the public's health:*
 - 1) Available models on projections of initiation, perpetuation of dependence and undermining of cessation related to menthol
 - 2) Unpublished epidemiological data (e.g., quitting, relapse, dependence by ethnic subgroups) and additional analyses of CDC data
 - a. Temporal trends, analysis of longitudinal trends in use and dependence from adolescence to adulthood
 - b. Examination of quit rates through quitline resources
 - 3) Primary data collection and assessment of existing resources examining smoke chemistries and clinical effects, consumer perceptions of messaging for mentholated products
 - 4) Data sets examining responsiveness of menthol smokers to pharmacologic therapies
 - a. Identification of menthol smokers in previous trials of pharmacologic therapies

* Potential resources: Legacy document reviewers, NCI research, published literature (e.g., CARDIA, Cohort Consortium)

Please see the transcript for detailed discussion.

3. (Discussion) Are there agenda items that should be included in future meetings pertaining to menthol?

- *The committee compiled a list of agenda items to be included in future meetings:*
 - 1) Population models relating to public health impact of menthol and potential ban on menthol as an additive, by population subgroups
 - 2) Targeted industry document reviews
 - 3) Additional CDC analyses and review of existing resources
 - 4) Examining impact of misleading descriptor ban (light/low/mild) on marketing terms for menthol products

Please see the transcript for detailed discussion.

4. (Discussion) What support does the Committee need to complete its report and recommendation by the statutory deadline?

- *The committee compiled a list of support items:*
 - 1) Literature review capabilities
 - 2) Reference management
 - 3) Facilitating Committee access to documents and primary source references, including establishment of web portal if possible
 - 4) Consultants with subject matter expertise (e.g., chemosensory effects, neurobiology)

Please see the transcript for detailed discussion.